REMARKS

The Present Application is a continuation of Serial No. 10/243,543 which was filed on September 12, 2002 and which is a continuation of Serial No. 09/293,366. Serial No. 09/293,366 was filed on April 16, 1999 and issued as U.S. Patent No. 6,623,494.

As discussed in the Interview on March 21, 2006, the Board of Patent Appeals and Interferences declared an Interference with respect to Serial No. 10/243,543 and U.S. Patent No. 6,391,038 on March 14, 2006. However, that Interference should have no effect on the patentability of the claims pending in the Present Application after entry of this Amendment. First, U.S. Patent No. 6,391,038 is not prior art to the Present Application because the Present Application is entitled to an earlier effective filing date. Secondly, the claims added by this Amendment would be patentable even if the claims of U.S. Patent No. 6,391,038 and the pending claim in Serial No. 10/243,543 were prior art. Accordingly, since the claims added by this Amendment are patentably distinct from those claims, allowance and issuance of these claims is appropriate even before a decision in the Interference.

By this Amendment, claims 1-20 are cancelled and new claims 21-100 are added. The newly added independent claims include claims 21, 37, 53, 69, and 85. Applicant extends appreciation for the discussion at the interview regarding the support in the Application for these independent claims and their patentability in light of U.S. Patent No. 6,113,612 issued to Swanson et al., U.S. Patent No. 5,993,468 issued to Rygaard, U.S. Patent No. 5,993,464 issued to Knodel, U.S. Patent No. 5,951,576 issued to Wakabayashi, U.S. Patent No. 5,732,872 issued to Bolduc et al., U.S. Patent

No. 5,695,504 issued to Gifford, III, et al., U.S. Patent No. 5,330,486 issued to Wilk, U.S. Patent No. 4,319,576 issued to Rothfuss.

Each claim is directed to a method for anastomosis of a graft vessel to a side of a receiving vessel. Independent claims 21 and 37 also indicate in their preambles that the method is limited to anastomosis of "an open end" of a graft vessel to a side of a receiving vessel. "Anastomosis" is used in the Application as it is conventionally used to refer to the union of vessels for fluid communication. Graft vessels, such as an autologous blood vessel or a synthetic graft, and receiving vessels, such as a blood vessel or other anatomical target vessel, are discussed in paragraphs 10-14 and 197 of the Application. Dependent claim 86 recites that the receiving vessel is a blood vessel and that the graft vessel is formed from a synthetic material.

Independent claims 21, 53, 69, and 85 recite "positioning an anvil within a lumen of a receiving vessel at an anastomosis site of the receiving vessel." Independent claim 37 recites "advancing an anvil inside and along a segment of a receiving vessel from an insertion site to an anastomosis site." Independent claims 21, 37, 53, 69 and 85 also recite that "the anastomosis site is located at a side of the receiving vessel." Support for these limitations is found at least at paragraphs 81-82, 140-168, 154, 198 and FIG. 1, FIGS. 15A-15B, FIGS. 17A-17B, FIG.18, and FIGS. 20-21 and the text accompanying these drawings.

Independent claim 21 recites that "the anastomosis opening is distinct from an opening used to achieve the introduction of the anvil into the lumen of the receiving vessel." Support for this limitation is located throughout the Application. FIG. 1 and the accompanying text provide a specific example. Dependent claim 34 recites that "the

anvil is removed via the opening used to achieve the introduction of the anvil into the lumen of the receiving vessel." Nearly identically, dependent claims 50, 66, 82 and 96 recite that "the anvil is removed via an opening used to achieve the introduction of the anvil into the receiving vessel." For example, as is clear from the Summary of the Invention at paragraphs 68-87, FIG. 1, and the diameter of anastomosis ring 300 shown in FIG. 15J relative to the ledge (discussed at paragraph 154) of anvil 160, the anvil is removed via "the opening used to achieve the introduction of the anvil into the lumen of the receiving vessel." Note that while anvils with ledges are removed via the insertion site, other anvils, such as those shown in FIG. 3A, FIG. 3D, and FIGS. 7A-7B, can also be removed via the graft vessel.

Each independent claim recites that a component extends from an anvil. The independent claims also recite that "the component extends through the wall of the receiving vessel." Examples of a component extending from the anvil include a wire or other structure such as a piercing wire which can be used to pull the anvil into position or a positioning stem, which can be used to push the anvil into position. Examples of support for the recitation of "a component extending from an anvil" are provided in paragraphs 142-147, 164-168, 195 and 268. Of course, other structures which extend from the anvil and enable the recited steps to be achieved would be apparent to a person of ordinary skill in the art based on the disclosure and are within the scope of the claims. Dependent claims 30, 46, 62, 78 and 94 recite that the component is a piercing wire. Dependent claims 31, 47, 63, 79 and 95 recite that the component is a positioning stem.

Independent claims 21 and 37 recite that the anvil is manipulated via the component. Support for this limitation is found at least in FIG. 1, FIGS. 15A-H, FIGS. 17A-17C, FIG. 18, FIGS. 20-21 and the accompanying text such as paragraphs 171, and 195-202. At least these same paragraphs and drawings, as well as paragraphs 81-82, also support the further limitation recited in independent claims 21 and 37, that manipulating the anvil via the component causes a "portion of the wall of the receiving vessel at the anastomosis site to stretch and to conform to the shape of a portion of the anvil contacting the wall of the receiving vessel." The ability "to cause a portion of the wall of the receiving vessel at the anastomosis site to stretch and to conform to the shape of a portion of the anvil contacting the wall of the receiving vessel" allows the portion of the wall to be more easily immobilized and it also makes it easier to cut the tissue when forming an anastomosis opening because it is tensioned. FIGS. 15A-15D shows a region of the wall stretching and conforming to the shape of a portion of the anvil at the anastomosis site as the anvil is manipulated via a component extending from the anvil such as piercing wire 150 which extends through a small puncture in the receiving vessel. Note that the puncture is much smaller than the anastomosis opening which is subsequently made in the receiving vessel for fluid communication between the graft vessel and the receiving vessel.

Dependent claims 28 and 44 recite that "the component extending from the anvil extends through the wall of the receiving vessel, before forming the anastomosis opening, in a configuration which permits the region of the wall to be caused to stretch and to conform to the shape of the portion of the anvil contacting the wall of the vessel without the anvil simultaneously passing through the wall. Dependent claims 65 and 92

have nearly the same language but do not include: "to stretch and." Dependent claim 76 recites that "the component extending from the anvil extends through the wall of the receiving vessel, before forming the anastomosis opening, in a configuration which permits the isolated portion of the wall to be stretched without the anvil simultaneously passing through the wall." At least the same support referenced in the above paragraph supports these recitations in dependent claims 28, 44, 65, 76, and 92.

The anvil can be pushed or pulled to cause the region of the wall of the receiving vessel at the anastomosis site to stretch and conform to the shape of the portion of the anvil contacting the wall of the receiving vessel. For example, positioning wire or stem 152 or positioning shaft 550 can be pushed or piercing wire 150 can be pulled. Dependent claims 25, 41, 57, 73, and 90 recite "forcing" a portion of the anvil against the wall of the receiving vessel.

Dependent claims 29, 45, 61, 77 and 93 recite that a portion of the anvil is convex. Support for this limitation is found at least in FIGS. 3C-3D, FIGS. 5-6 and FIGS. 7A-7B.

Independent claims 53, 69 and 85 each recite "holding a portion of the wall of the receiving vessel at the anastomosis site between the anvil and a component of an extravascular device." Examples of extravascular devices are described at paragraph 140 of the Application as including endoscopic devices and peripheral devices such as device 200. A generalized example of the use of extravascular devices is provided at paragraph 83. Support is also provided at least by FIGS. 8, FIGS. 9A-9C, FIGS. 10-14, FIGS. 15A-15J, FIGS. 17C-17I, FIG. 18, FIGS. 20-21 and the corresponding text in the Application for the limitations recited in independent claims 53, 69 and 85 with respect

to an extravascular device. An example of "a component" of an extravascular device as referenced in these independent claims is provided by anastomosis ring 350, which is best appreciated with reference to FIG. 9A and FIG. 13. As shown in FIG. 15D and FIG. 15E, a portion of the wall of the receiving vessel is held between anvil 160 and anastomosis ring 350. As described at paragraphs 198-199 of the Application, and as shown in the referenced figures, anvil 160 is pulled by piercing wire 150 while anastomosis ring 350 is either urged in the opposite direction or held stationary. As stated in paragraph 199 and as best shown in FIG. 15E, this action results in the outer wall of receiving blood vessel 99 and the inner wall of graft vessel 98 being "held between inner side wall 314 of anastomosis ring 350 and an embodiment of the anvil's surfaces such as any of surfaces 164-167." This action is also characterized in the Application at paragraph 187 as "forcing the surfaces of the graft vessel and the receiving blood vessel against each other." Stated otherwise, the receiving vessel is held between the anvil and anastomosis ring 350. FIGS. 20-21 depict other embodiments of a method that involves "holding a portion of the wall of the receiving vessel at the anastomosis site between the anvil and an extravascular device." The above text and drawings are examples of support for the recitation in independent claims 53, 69 and 85 that a portion of the wall of the receiving vessel is held "at the anastomosis site between the anvil and a component of an extravascular device." Other examples of components of an extravascular device within the scope of these claims are shown in FIGS. 17D-17F, FIG. 20 and FIG. 21. FIGS. 17D-17F show that the inner diameter of each sector 670 and, to a lesser extent, clips 695 hold a portion of the wall of the receiving vessel "between the anvil and a component of an extravascular

device." In FIG. 21, the ends of tubular graft vessel holder 177 and a segment of the surfaces forming the inner diameter of tubular graft vessel holder 177 cooperate with the anvil to hold a portion of the wall of the receiving vessel.

Additionally, independent claims 53, 69 and 85 each recite that "the component of the extravascular device is positioned outside of a graft vessel lumen." FIG. 15E provides an example of a component of an extravascular device which is positioned outside of a graft vessel lumen. In particular, FIGS. 15C-15E shows anastomosis ring 350 which is positioned outside of the lumen of graft vessel 98. The features discussed above with respect to in FIGS. 17D-17F, FIG. 20 and FIG. 21 provide additional examples of a component of an extravascular device which is positioned outside of a graft vessel lumen.

Independent claim 53 recites "holding a portion of the wall of the receiving vessel at the anastomosis site between the anvil and a component of an extravascular device while causing a region of the wall to conform to the shape of a portion of the anvil contacting the region such that at least part of the region extends beyond the portion of the wall held between the anvil and the component of the extravascular device." An example of part of the region of the wall extending "beyond the portion of the wall held between the anvil and the component of the extravascular device" is shown in FIG. 15E. As discussed above, an example of the portion of the wall of the receiving vessel which is held between the anvil and the component of the extravascular device is the tissue of receiving blood vessel 99 shown in FIG. 15E held between inner side wall 314 (as shown best in FIG. 13) of anastomosis ring 350 and the surface of the anvil such as one of the side surfaces identified at 164-167 in FIGS. 3A-3C. Support for "causing a region

of the wall to conform to the shape of a portion of the anvil" has already been discussed. FIG. 15E shows tissue of receiving blood vessel 99 on the receiving surface (other examples of receiving surfaces 162 are shown in FIGS. 3A-3D) of anvil 160. The tissue on the receiving surface in FIG. 15E is an example of at least part of the region of the wall extending beyond the held portion.

Independent claim 69 recites "holding a portion of the wall of the receiving vessel at the anastomosis site between the anvil and a component of an extravascular device to isolate a region of the wall and to stretch at least part of the isolated region prior to forming an anastomosis opening." Support for the isolation of "a region of the wall" and stretching "at least part of the isolated region prior to forming an anastomosis opening" is found at least in the drawings and text of the Application discussed above. For example, an isolated region in FIG. 15E is the tissue of receiving blood vessel 99 within the perimeter of the portion which is held between the side surface of anvil 160 and inner side wall 314 of anastomosis ring 350. Other examples of support for stretching "at least part of the isolated region" are found in the other figures in the series identified as FIGS. 15A-15H and the accompanying text for these figures. Support is also found at least in FIG. 17F, FIGS. 20-21 and the accompanying text.

Independent claim 85 recites "holding a portion of the wall of the receiving vessel at the anastomosis site between the anvil and a component of an extravascular device while causing at least part of a region of the wall to extend into the lumen of a graft vessel." FIG. 15E shows at least part of a region of the wall of receiving blood vessel 99 extending into the lumen of graft vessel 98. Other examples of support for "causing at least part of a region of the wall to extend into the lumen of a graft vessel" are found

in the other figures in the series identified as FIGS. 15A-15J, FIG. 17F, FIGS. 20-21 and the accompanying text for these figures. Note that, as shown in FIG. 15G, at least part of a region of the wall extends into the lumen of a graft vessel as the graft vessel is joined to the receiving vessel. Note also that, as shown in FIG. 15J, at least part of a region of the wall extends into the lumen of a graft vessel even after the anastomosis opening has been formed. Dependent claims 27, 43, 59 and 75 are also supported at least by the same figures and text in the Application.

Dependent claims 26, 42, 58, and 74 and 91 recite that a part of the region of the wall of the receiving vessel extends into an opening of an extravascular device "prior to forming the anastomosis opening and remains in the opening of the extravascular device as the graft vessel is joined to the side of the receiving vessel." Some examples of an opening in a component of an extravascular device include: the opening defined by the inner diameter of anastomosis ring 350 in FIG. 15C, the opening defined by the inner surfaces of each sector 670 in FIGS. 17D-17F, and the opening defined by the inner diameter of tubular graft vessel holder 177 in FIG. 21. Additional support for the recitation in 26, 42, 58, and 74 and 91 is found at least in FIGS. 15D-H, FIGS. 17C, FIGS. 20 and the accompanying text such as paragraphs 171, 195, 198-199.

Independent claims 21, 37, 53, 69 and 85 recites "joining a graft vessel to the side of the receiving vessel at the anastomosis site." Stapling is an example of a technique for joining the vessels together. Independent claim 85 also recites that the graft vessel is joined to the side of the receiving vessel at the anastomosis site by "driving staples through graft vessel and through the wall of the receiving vessel while the part of the region of the wall extends into the lumen of the graft vessel, wherein the

staples are driven against the anvil." Dependent claims 32-33, 48-49, 64-65, 80-81 and 97-98 relate to stapling. Support for the limitations recited in these claims is found at least in FIG. 3B, FIGS. 9A-9B, FIGS. 15D-15L and the corresponding text such as paragraph 200.

Independent claims 21, 37 and 53 recite "forming an anastomosis opening in the wall of the receiving vessel at the anastomosis site." Many techniques are disclosed in the Application for forming an opening. Independent claims 69 and 85 recite "cutting the wall of the receiving vessel to form an anastomosis opening in the side of the receiving vessel at the anastomosis site." It would be apparent to a person of ordinary skill in the art based on the Application that an anastomosis opening can have many shapes and be formed in many different ways. Support is found at least in paragraphs 201 and 204 of the Application for the recitation that the steps of joining vessels together and forming an anastomosis opening can have alternative sequences. Dependent claims 22-23, 38-39, 54-55, 70-71 and 87-88 recite these alternative sequences. Of course the ability to do these two steps in either sequence makes it apparent to a person of ordinary skill in the art that these steps may also simultaneously occur. This position is further supported by the sequential images provided in FIGS. 15D-15J and the accompanying text. Dependent claims 24, 40, 56, 72 and 89 recite the simultaneous occurrence of these two steps.

Dependent claims 35, 51, 67, 83 and 99 recite that "that the receiving vessel is a blood vessel" and that the anastomosis opening is formed "without substantially blocking blood flow through the receiving vessel." Dependent claims 36 and 52 recite that "the receiving vessel remains pressurized as the graft vessel and the receiving

vessel are anastomosed together." Dependent claim 68, 84, and 100 recites that "the anvil is positioned at the anastomosis site while the receiving vessel remains pressurized, wherein the anvil enables the receiving vessel to remain pressurized as the graft vessel is joined to the side of the receiving vessel and as the opening is formed in the receiving vessel at the anastomosis site." Examples of support for these limitations are found in the Application in paragraphs 71, 78, 166 and 224. Support is also found in FIGS. 15A-15H and the corresponding text. In the Background section of the Application at paragraph 14, it is explained that "most conventional techniques for vascular anastomosis require the interruption of blood flow through the receiving vessel while the anastomosis is performed." It is stated in the Summary and Objects of the Invention section of the Application at paragraph 71 that it is an object of the invention "to enable the performance of minimally invasive anastomoses that do not require the interruption of blood flow in the receiving blood vessel." One of the advantages resulting from the continued blood flow, as identified in the Summary and Objects of the Invention section of the Application at paragraph 78, is that the risk of ischemia is reduced or even eliminated in organs that receive their main supply of blood through the receiving vessel.

In the section of the Application titled Detailed Description of the Preferred Embodiments at paragraph 143, an overview is provided of the conventional catheterization techniques used to insert the anvil into a pressurized receiving vessel with reference to FIG. 1. Vascular sheaths with hemostatic valves are commonly used devices which allow insertion of catheters and other endovascular devices into pressurized receiving vessels. One of ordinary skill in the art would understand that use

of these conventional catheterization techniques enables an anvil to be inserted into a pressurized receiving vessel.

One of the reasons that it is not necessary to block the flow of fluid through the receiving vessel during the procedure is the small size of the puncture made by the piercing wire 150 extending from anvil 160 when piercing wire 150 extends through vessel 99. The puncture is small enough to prevent significant bleeding through the puncture. Piercing wire 150 is described in the Application as "puncturing" the vessel in paragraphs 143-144, 164 and 168; as "penetrating" the vessel in paragraph 144 and as "perforating" the vessel in paragraph 195. As described in paragraph 144, the piercing wire can be any "thin and elongated device that is used for penetrating the wall of a blood vessel." The puncture formed by the piercing wire is very small compared with the perimeter of the anastomosis opening. The anastomosis opening is large enough to allow blood flow between the graft vessel and the receiving vessel. The relatively small size of the puncture compared to the size of the anastomosis incision is well understood with reference to FIG. 15H and the description provided in paragraph 201. The paragraphs and drawings which support the "pressurized" limitation also support the limitation recited in dependent claims 35, 51, 67, 83 and 99 which make reference to the fluid flow through the receiving vessel not being substantially blocked.

As is well know, the tissue of a blood vessel has resilience. This resilience, among other tissue properties, enables the puncture to be formed without substantial blood loss. The skilled artisan would understand, based on the Application, that an anvil positioned in the receiving vessel with its piercing wire or other structure with a small diameter extending out of a puncture yields a seal which prevents loss of

pressurization of the vessel. Because the resilient blood vessel seals around the piercing wire, it is not necessary to clamp the blood vessel or to otherwise interrupt the flow of blood. Since it is not necessary to interrupt the flow of blood, the receiving vessel can be pressurized.

Another reason that the receiving vessel can be pressurized is the small diameter of the piercing wire relative to the size of the anvil. An additional reason that the receiving vessel can remain pressurized is the shape of the anvil. The anvil is sized and shaped to substantially block blood flow out of the puncture made by the piercing wire. The anvil size and shape augment the sealing effect achieved by the inherent properties of the tissue of the blood vessel since the anvil seals the puncture as the anvil is positioned adjacent the interior of the wall of the pressurized receiving vessel. Note that the anvil also permits forming an anastomosis opening in the receiving vessel at the anastomosis site while substantially blocking fluid flow from the receiving vessel to the graft vessel at the anastomosis site without substantially blocking flow through the receiving vessel. The receiving vessel remains pressurized as recited in dependent claims 36, 52, 68, 84, and 100 due to the small size of the puncture made by the piercing wire 150, the resilience of the receiving vessel, and the small diameter of the piercing wire relative to the size of the anvil and the shape of the anvil.

In summary, the new claims are supported at least by the drawings and text of the Present Application which are specifically discussed above. Also, the claims recite key improvements over the prior art which are achieved by several features. In view of the foregoing, it is believed that all of the claims are patentable in their present form, and a prompt notice of allowance for this case is respectfully requested. As mentioned above, if the Examiner finds any remaining impediment to the prompt allowance of this application, please contact the undersigned attorney.

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Respectfully submitted,

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